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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/851,873	05/08/2001	Rolf F. Kletzien	28341/00233.NCP	4967
4743	7590	11/17/2003	EXAMINER	
MARSHALL, GERSTEIN & BORUN LLP			HUTSON, RICHARD G	
6300 SEARS TOWER			ART UNIT	
233 S. WACKER DRIVE			PAPER NUMBER	
CHICAGO, IL 60606			1652	

DATE MAILED: 11/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

09/851,873

Applicant(s)

KLETZIEN ET AL.

Examiner

Richard G Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/5/2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-3,5,7 and 8 is/are rejected.
- 7) ☐ Claim(s) 4 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/5/2003 has been entered.

Applicants amendment of claims 1, 2 and 3, Paper of 9/5/2003, is acknowledged. Claims 1-49 are at issue and are present for examination.

Applicants' arguments filed on 9/5/2003 have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claims 6 and 9-49 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 8.

Priority

Applicants claim of the benefit of U.S. Provisional application 60/203,162, filed May 9, 2000, is again acknowledged and it noted that applicants are **not** granted priority for the amino acid sequence of SEQ ID NO: 77 to U.S. Provisional application 60/203,162, thus SEQ ID NO: 77 is only granted priority to the instant application.

Claim Objections

Claim 4 is objected to because of the following informalities:

Claim 4 is dependent on rejected claim 1.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The rejection of claim 7 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is hereby withdrawn in light of applicants amendment of claim 7 to include the recited "moderately stringent hybridization conditions" from page 27 of the specification . These conditions are not to be confused with the "highly stringent conditions" recited on the same page.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5, 7 and 8 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a caspase polypeptide comprising the amino acid sequence of SEQ ID NO: 77, does not reasonably provide enablement for any caspase polypeptide comprising an amino acid sequence at least 98% identical to the amino acid sequence of SEQ ID NO: 77, wherein said polypeptide comprises a QACXG domain and possesses caspase activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The rejection was stated in the previous office actions, as it applied to claims 1-3, 5, 7 and 8. In response to this rejection, applicants have amended claims 1-3, 5, 7 and 8 and traverse the rejection as it applies to the amended claims.

Applicants amendment of the rejected claims to recite that the claimed caspases are 98%, 95% and 90% homologous to a sequence of SEQ ID NO: 77, possess caspase activity and further contain the QACXG sequence. It is noted that applicants appear in their arguments to mistakenly refer to this penta-peptide as "QACGX" rather than "QACXG".

Besides the above amendment applicants do not comment as to why applicants believe "this amendment obviates all of the rejections based on 35 U.S.C. 112 first paragraph for lack of enablement, and thus the rejection is maintained for the reasons previously stated.

While methods to produce variants of a known sequence such as site-specific mutagenesis, random mutagenesis, etc. are well known to the skilled artisan producing variants as claimed by applicants (i.e., merely having 90% identity to the amino acid sequence of SEQ ID NO: 77, and comprising a QACXG domain) requires that one of ordinary skill in the art know or be provided with guidance for the selection of which of the claimed number of variants that have the claimed property. Without such guidance one of ordinary skill would be reduced to the necessity of producing and testing all of the possibilities. This would clearly constitute undue experimentation. While enablement is not precluded by the necessity for routine screening, if a large amount of screening is required, the specification must provide a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. Such guidance has not been provided in the instant specification. As previously stated the specification does not **sufficiently** establish: (A) regions of the protein structure which may be modified without effecting caspase activity; (B) the general tolerance of caspases to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residue of any caspase variant of SEQ ID NO: 77, with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any number of amino acid modifications

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of a caspase comprising the amino acid sequence of SEQ ID NO: 77, wherein said caspase polypeptide comprises the amino acid sequence QACXG. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of those polypeptides having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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A handwritten signature in black ink, appearing to read 'Richard G. Hutson', with a large, stylized loop at the end.

Richard G Hutson, Ph.D.
Primary Examiner
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rg
11/12/2003